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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LANG, AMY T	
ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/753,848	TRABADA ET AL.	
	Examiner	Art Unit	
	AMY LANG	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-13,22,24 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 10-13, 22, 24, and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1-5, 7, 10-12, and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter (EP 0,976,417 A1) in view of Cohen et al. (US 5,167,239) and Middleman et al. (US 7,169,160 B1).

With regard to **claim 1**, Ritcher discloses a guidewire (2) which, when in an operative position, extends through a body lumen to a desired location and therefore overlaps the instantly claimed guide track ([0010]). Catheter (15) comprises a modular device disposed over and therefore coupled to the guidewire ([0018]). The catheter can be removed from the guidewire so that it is selectively coupled to the guidewire. Ritcher further teaches that the catheter comprises a drive mechanism (1) that engages the

guidewire to move the catheter along the guidewire ([0019]). The drive mechanism "crawls" along the guidewire to move the catheter along the guidewire ([0016]; [0019]).

Ritcher teaches the guide wire is secured in place before the modular device crawls along it to the target location ([0019]). However, Ritcher is silent as to how the guide wire is secured and anchored.

Cohen et al. (hereinafter Cohen) discloses a guidewire with a distal anchoring device (Figure 1). A balloon (14) located on the distal end of the balloon is inflated to anchor and secure the guidewire at the desired location within a patient's lumen (column 3, lines 29-36).

However, Cohen does not specifically disclose the balloon as moveable on the guidewire. Middleman et al. (hereinafter Middleman) teaches that it is well known and advantageous for an anchoring means to move along a guide track, tubular element (18), and be deployed at various locations along the guide track (Figures 1 and 10-13; column 10, line 64 through column 11, line 15). This gives more flexibility to the use of the guide track. Once deployed, the anchor secures a guide wire in place in a vessel (Figures 4 and 5; column 5, lines 9-14; column 6, lines 14-17). Ritcher teaches an advantageous method to introduce devices into the body along a guidewire that does not rely on the “pushing” mechanism of Middleman ([0002]). Ritcher specifically teaches introducing devices with a motor drive mechanism to crawl along the guidewire ([0015]). Therefore, the device is able to crawl to any desired position along the length of the guidewire ([0016]).

Since Ritcher is silent as to how the guidewire is secured and Cohen teaches a balloon anchoring mechanism to anchor guidewires within a patient's vessel, it would have been obvious to one of ordinary skill in the art at the time of the invention for Ritcher to use a balloon anchoring device. Given that Middleman teaches an anchoring device that would move along the guidewire of Cohen and Ritcher teaches an advantageous method to move the anchor, it would have been obvious to one of ordinary skill in the art for the anchoring balloon to also crawl along the guide wire by a drive mechanism as claimed. This would produce a drive mechanism located inside the Cohen balloon.

With regard to **claim 2**, the guide track (2) of Ritcher is specifically disclosed as a guidewire.

With regard to **claim 3**, as shown in Figures 1 and 2 of Ritcher, the guidewire comprises a substantially helical surface. Additionally, Cohen teaches that helically coiled wires are well known in the art (column 1, lines 19-23).

With regard to **claim 4**, the drive mechanism (1) of the catheter (15) is specifically disclosed as a motor ([0015]).

With regard to **claim 5**, Ritcher discloses the drive mechanism as a miniature oscillating motor, which an electric motor encompasses (see paragraph [0001] of Strobl (US 2004/0183383 A1)).

With regard to **claim 7**, Ritcher further discloses the catheter as comprising a guide track receiving lumen (18) ([0018]).

With regard to **claims 10 and 11**, the balloon of Cohen is the extendible member and component 26 of Cohen overlaps the inflation lumen.

With regard to **claim 12**, catheter (15) of Ritcher, the modular device, also comprises a balloon (19) located on the exterior of the device (Figure 7). The balloon is expanded to deploy the stent, but is also capable of anchoring the modular device within a patient's lumen ([0019]). Therefore, balloon (19) overlaps the instantly claimed second extendible member.

With regard to **claim 13**, it is the examiner's position that the balloon (19) on the exterior of the catheter intrinsically comprises an inflation lumen. This is well known in the art to expand a balloon.

4. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Richter (EP 0,976,417 A1) in view of Cohen (US 5,167,239) and Middleman (US 7,169,160 B1) as applied to claim 1 above, and further in view of Kindlein (US 7,229,401 B2) or Ziegler et al. (US 6,971,990 B2).

Ritcher in view of Cohen and Middleman disclose a modular device, comprising a motor, moveably disposed on a guidewire. However, Ritcher does not specifically disclose the movement between the two components as activated by gears.

Kindlein, as shown in Figure 6, discloses a moveable needle advanced and retracted within a housing due to moveable and interacting wheels. Although not specifically shown, it would have been obvious for the wheels to comprise threaded gears for more accurate movement. Zielger et al. (hereinafter Ziegler) also shows

movement between threaded gears to advance an object (Figures 1 and 5). Additionally, Ritcher discloses an electric motor to move the catheter. Merely replacing the electric motor with a mechanical action simplifies the device and allows it to safely enter a patient. Since a drive mechanism utilizing gears to move an object along a track is well known in the art, as taught by Kindlein and Ziegler, it would have been obvious to one of ordinary skill in the art at the time of the invention for the drive mechanism of Ritcher to be simplified into a gear mechanism.

5. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over Richter (EP 0,976,417 A1) view of Kindlein (US 7,229,401 B2) or Ziegler et al. (US 6,971,990 B2).

Ritcher, as discussed in paragraph 3 and incorporated here by reference, discloses a modular device driven by a drive mechanism over a guide track. The drive mechanism comprises a motor that engages the guide track to advance the modular device along the guide track.

Ritcher does not specifically disclose the drive mechanism as a threaded member that rotationally engages the guide track. Kindlein, as shown in Figure 6, discloses a moveable needle advanced and retracted within a housing due to moveable and interacting wheels. Although not specifically shown, it would have been obvious for the wheels to comprise threaded gears for more accurate movement. Zielger et al. (hereinafter Ziegler) also shows rotational movement between threaded gears (138, 140, 134, etc.) to advance an object (Figures 1 and 5). As shown in Figure 5, the

threaded gears form a threaded hole that interacts with gear members (542). Additionally, Ritcher discloses an electric motor to move the modular device. Merely replacing the electric motor with a mechanical action simplifies the device and allows it to safely enter a patient. Since a drive mechanism utilizing gears to move an object along a track is well known in the art, as taught by Kindlein and Ziegler, it would have been obvious to one of ordinary skill in the art at the time of the invention for the drive mechanism of Ritcher to be simplified into a threaded gear mechanism.

6. **Claims 22, 24, and 25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritcher (EP 0,976,417) in view of McAlister et al. (US 2002/0065523), Cohen (US 5,167,239), and Middleman (US 7,169,160 B1).

With regard to **claim 22**, Ritcher, as discussed in paragraph 3 and incorporated here by reference, discloses a modular device driven by a drive mechanism over a guide track. The modular device comprises an expandable balloon. The drive mechanism comprises a motor that engages the guide track to advance the modular device along the guide track.

Ritcher does not specifically disclose the modular device used for resecting tissue or an anchoring module.

McAllister discloses a modular device (1) that moves along a guidewire (3) to the desired location ([0029]). At this point, a window (20) on the modular device draws in tissue and then severs the tissue ([0030]; [0033]; Figure 3C). Therefore, McAllister teaches a modular device that resects tissue. It would have been obvious at the time of

the invention for the modular device of Ritcher to comprise a tissue resection device, as disclosed by McAllister, which would crawl along a guidewire. This would be a convenient manner in which to guide the tissue resection modular device into position without causing it to buckle which can occur during pushing.

Although Ritcher does not specifically disclose the guidewire comprising an anchoring module, Cohen discloses a guidewire with a distal anchoring balloon (Figure 1). A balloon (14) located on the distal end of the balloon is inflated to anchor and secure the guidewire at the desired location within a patient's lumen (column 3, lines 29-36).

However, Cohen does not specifically disclose a motor to advance the anchoring balloon along the guidewire. Middleman, as discussed above, teaches that it is advantageous for an anchoring device to move along a guide track so that it can deploy and anchor at various locations. Ritcher, as discussed above, teaches an advantageous system to move device along a guide track so that they can crawl along the track instead of being pushed. Therefore, it would have been obvious at the time of the invention for the anchoring balloon to also comprise a module that can crawl along the guidewire to the distal location. This would allow the anchoring balloon to be advanced to the desire position after the guidewire is in place, which reduces trauma to the patient rather than advancing the balloon and guidewire simultaneously.

Therefore, Ritcher in view of McAllister, Cohen, and Middleman discloses a method of resecting tissue wherein an anchoring balloon module is advanced over a guidewire to the desired location and then expanded to secure the guidewire in place.

A tissue resecting modular device is then advanced over the guidewire. The device then resects tissue and is then retracted proximally.

With regard to **claim 24**, when the anchoring balloon is expanded, the anchoring module is extended to thereby anchor the guide track.

With regard to **claim 25**, member (50) of McAllister attaches and grasps onto the tissue (Figure 3C). Therefore, before the tissue is completely cut, member (50) overlaps the claimed positioning device since it holds onto the tissue and therefore maintains the modular device in a certain position.

Response to Arguments

7. Applicant's arguments filed 08/13/2010 have been fully considered but they are not persuasive.

Applicant first argues that Middleman does not teach anything capable of meeting the limitation of "an anchoring module drive for engaging the guide track to move the anchoring module along the guide track to the desired location." The Examiner agrees since Middleman is used to show that it is well known for an anchoring means to move along a guide track (18) to secure the guide track (18) at various locations (noting that the Examiner relies on member 18 for the guide track while Applicant argues with reference to member 46 for the guide track). The combination of Cohen, Middleman, and Ritcher is used to yield the claimed anchoring module. Cohen specifically teaches an anchoring balloon for securing a guide track. Middleman teaches an anchoring module that moves with respect to a guide track. Ritcher teaches a modular device that is directly coupled with a guide track to move the device along the

guide track. Therefore, the combination of Cohen, Middleman, and Ritcher show that a balloon that moves along a guide track through a direct coupling to the guide track is obvious to one of ordinary skill in the art.

Applicant also argues that neither Kindlein nor Ziegler teaches a threaded member for engaging a contact surface of the guide track and rotating about the guide track. However, as discussed above, Kindlein teaches drive wheels (31, 33a, 33b, 33c, 33d) that create a hole through which a needle is advanced and retracted. Therefore, Kindlein teaches wheel members that can guide and move a needle so that it would have been obvious for Ritcher to also use wheel members to guide and move along the guide track. Although Kindlein does not teach the wheels as threaded, such is well known in the art to produce movement. Additionally, Zeigler also shows threaded wheel members (542) that produce movement rotational movement along a guide track.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10/13/2010
/AMY LANG/
Examiner, Art Unit 3731

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10/13/10